

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

COLUR WORLD, LLC,

Plaintiff

v.

SMARTHEALTH, INC.,
SMARTPRACTICE, INC. and
MEDISAFE TECHNOLOGIES,

Defendants

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Case No. 2:09-cv-00505

Honorable Joel H. Slomsky

**DEFENDANTS SMARTHEALTH, INC. AND SMARTPRACTICE'S
MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION
TO DISMISS PLAINTIFF'S COMPLAINT**

Pursuant to Federal Rule of Civil Procedure 12(b)(6) and Civil Local Rule 7.1, Defendants SmartHealth, Inc. and SmartPractice (collectively, "SmartHealth"), by their undersigned counsel, hereby submit this Memorandum in support of their Motion to Dismiss the complaint of Plaintiff, Colur World, LLC ("Colur World").

INTRODUCTION

Colur World claims it has an exclusive right to use the color pink and the word "pink" in the medical and dental nitrile glove market. Yet, in 2005 and 2006 the United States Patent and Trademark Office (the "USPTO") rejected Colur World's claim that it had become known as the "pink nitrile glove people," finding instead that Colur World did not have any such exclusive rights because the color pink and the word "pink" were functional, ornamental and not distinctive. Simply put, the fact that a nitrile glove is pink or that it is described as "pink nitrile" does not tell consumers that the glove must have come from Colur World.

Colur World's claims are no stronger now. In fact, they are even weaker. Since 2005, Colur World has inconsistently marketed its nitrile gloves using the marks PINK NITRILE, BLUE NITRILE, NITRASTRETCH, NITRAFLEX and 2ndSKIN. Colur World also has marketed nitrile gloves in the colors pink, "subtle lavender" and blue since 2005. The color of the packaging of its nitrile gloves bearing its COLOR PINK and PINK NITRILE marks has also fluctuated from light pink to coral and, most recently, to white. This inconsistent marketing has only degraded Colur World's already weak claims.

Despite this, Colur World now seeks to restrain SmartHealth from selling its own pink nitrile gloves as part of its "Pink Ribbon, Gloves of Hope" campaign for breast cancer awareness, and from describing the gloves' pink color on the package.

Colur World cannot succeed on its claims. Among other reasons, the color pink and the word "pink" are functional, ornamental and descriptive features of these gloves, and Colur World has not developed any secondary meaning of these features. Because Colur World has not alleged (and cannot) that it has any protectable rights in its COLOR PINK and PINK NITRILE marks, SmartHealth respectfully requests that the Court grant this Motion, and dismiss Colur World's Complaint.

BACKGROUND¹

The Parties

Both Colur World, through its licensee and predecessor in interest,² and SmartHealth market and sell medical grade gloves made of nitrile for use by medical and dental professionals.

¹ SmartHealth denies many of the allegations made in Colur World's complaint, but only accepts them as true for purposes of this motion, as required by Rule 12(b)(6).

(Compl., Dkt #1, ¶¶ 14, 23-26.) Nitrile gloves are a popular alternative to other glove types that may potentially cause allergic reactions. (*See id.* at ¶ 14.) Unlike traditional natural rubber gloves, nitrile does not contain any allergenic, water-based latex proteins, making nitrile gloves less likely to cause allergic reactions in users and patients. (*Id.*)

Colur World states in its Complaint that it began using the color pink as trade dress (identified as the COLOR PINK mark) and the trademark PINK NITRILE in connection with a nitrile glove product line on April 26, 2005. (*Id.* at ¶ 15.) Colur World sells nitrile gloves bearing the COLOR PINK and PINK NITRILE mark for \$6.00 to \$7.00 per box. (*Id.* at ¶ 17.)

According to Colur World's Complaint, SmartHealth began selling pink nitrile gloves prominently bearing its own distinctive marks PINK RIBBON and GLOVES OF HOPE in 2008. (*See id.* at ¶ 24, Exhibit B.) SmartHealth sells its nitrile gloves bearing its marks PINK RIBBON and GLOVES OF HOPE for \$7.99 per box. (*Id.* at ¶ 26.) As part of its PINK RIBBON, GLOVES OF HOPE campaign, SmartHealth donates five-percent of the income generated from its sales to breast cancer research. (*Id.* at Exhibit B.)

Colur World's Marks Rejected on the Principal Register

Eight days after Colur World began using the COLOR PINK and PINK NITRILE marks in commerce, it applied to register its marks on the Principal Register. (Dornberger Decl.,

² Colur Word licensed the right to use its marks to its predecessor in interest, Top Quality Manufacturing, Inc. (Comp., Dkt #1, ¶ 12.) Both are referred to herein as Colur World.

(05/08/2009), May 4, 2005 Applications for Registration of PINK NITRILE & COLOR PINK, Ex. 1.)³

The USPTO rejected Colur World's application to register the marks on the Principal Register. Among other things, the USPTO objected because the color pink was both functional and ornamental as used on nitrile gloves, stating "purchasers do not initially view such use of color as a trademark for the goods but as ornamentation." (December 9, 2005 Office Action – COLOR PINK, Ex. 2, at p. 2.) The USPTO also rejected Colur World's application because of the lack of distinctiveness of both the color and the term "pink." (*Id.* at p. 3; December 1, 2005 Office Action – PINK NITRILE, Ex. 5, at p. 3.) As to the PINK NITRILE mark, the USPTO stated that the words pink and nitrile serve to "describe[] a characteristic and quality of the goods." (December 1, 2005 Office Action – PINK NITRILE, Ex. 5, at p. 4.) The words do not identify a source of origin, as would be required for Colur World to have protectable rights.

In response to the USPTO's objection to registering these marks, Colur World submitted a declaration from its President identifying the sales and advertising expenses of its nitrile gloves bearing the marks COLOR PINK and PINK NITRILE.⁴ The USPTO rejected these arguments

³ All further references to "Ex. __" are referred to in the May 8, 2009 Declaration of John W. Dornberger accompanying SmartHealth's Motion to Dismiss Plaintiff's Complaint. All documents referenced in the Declaration are public records of Colur World's trademark registration files and can be found at <http://tportal.uspto.gov/external/portal/tow>. However, Movant has provided courtesy copies of all of the documents referenced in the Declaration to the Court and served copies of the same on counsel for Plaintiff concurrent with the filing of the instant Motion. The Court can consider these public records on a motion to dismiss. *See Liko AB v. Rise Lifts, Inc.*, No. 07-5302, 2008 WL 5250488, at *2 (E.D. Pa. Dec. 15, 2008); *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, No. 2:04-cv-975, 2005 WL 6127327, at *3 (W.D. Pa. Aug. 22, 2005) ("The Brief in Opposition to Cancellation is relevant to the Motion to Dismiss, and as a public record may be, and has been, considered by the Court.").

⁴ (*See* June 8, 2006 Response to December 9, 2005 Office Action, Ex. 3, at p. 3-7; and June 5, 2006 Response to December 1, 2005 Office Action, Ex. 6, at p. 14-18.)

as well, and again refused to allow Colur World to register these marks on the Principal Register. As to the PINK NITRILE mark, the USPTO ruled that "the evidence [submitted] as a whole does not demonstrate success in educating the public to associate the word PINK with a single source" and that "the word PINK simply designates the color of the goods, and not the source of the goods." (July 12, 2006 Office Action – PINK NITRILE, Ex. 7, at pp. 2-3.) As to the COLOR PINK, the USPTO ruled that the evidence submitted was "merely indicative of [Colur World's] efforts to develop distinctiveness, not evidence that the mark has acquired distinctiveness." (August 16, 2006 Office Action – COLOR PINK, Ex. 4, at p. 2.) The USPTO also determined that the COLOR PINK was not viewed as a trademark, but merely as ornamentation. (*Id.* at p. 3.)

Colur World's Use of the COLOR PINK and PINK NITRILE Marks

Even since the USPTO rejected Colur World's attempts to register its marks, Colur World has failed to develop its self-described image as "the pink nitrile glove people." Colur World sells nitrile gloves in several different colors – pink, blue and "subtle lavender." (Compl., Dkt #1, Exhibit A; June 8, 2006 Response to December 9, 2005 Office Action, Ex. 3, at p. 9.) And it has marketed these gloves in packaging prominently bearing several different names – NITRASTRETCH, NITRAFLEX and 2ndSKIN. (Compl., Dkt #1, Exhibit A; June 5, 2006 Response to December 1, 2005 Office Action, Ex. 6, at Exhibit 3.) Even the color of Colur World's packaging for its nitrile gloves bearing the marks COLOR PINK and PINK NITRILE has fluctuated since 2005 from light pink, to coral and, most recently, to white. (Compl., Dkt #1, Exhibit A; June 5, 2006 Response to December 1, 2005 Office Action, Ex. 6, at Exhibit 3.) Thus, nothing in Color World's branding scheme suggests a consistent campaign to educate its customers as to the use of the COLOR PINK and PINK NITRILE as a source identifier.

Colur World's Complaint

Colur World's Complaint seeks to prevent SmartHealth from selling its nitrile gloves as part of its PINK RIBBON, GLOVES OF HOPE campaign. However, the Complaint merely asserts legal conclusions that Colur World "use[s] the COLOR PINK Mark as a source of origin," that "the Colur World Marks have acquired trademark distinctiveness," and that, as a result, SmartHealth's PINK RIBBON and GLOVES OF HOPE campaign will likely cause consumer confusion. (Compl., Dkt #1, ¶¶ 13, 20, 35, 43-45.) But nowhere in its Complaint does Colur World ever allege that use of the color pink on gloves (its own use or SmartHealth's) is non-functional. And Colur World does not allege any facts to demonstrate that its marks have acquired the distinctiveness and secondary meaning that the USPTO already found they lacked—in other words, how an otherwise inconsistent marketing and branding scheme has educated consumers to consider Colur World "the pink nitrile glove people."

ARGUMENT

A Rule 12(b)(6) motion to dismiss tests the legal sufficiency of the allegations in a complaint. Although a court must accept as true all of the well-pled allegations in the complaint, it is not required to accept a complaint's "bald assertions" or "legal conclusions." *Morse v. Lower Merion School Dist.*, 132 F.3d 902, 906 (3d Cir. 1997). *See also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) ("[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do."). Courts can and should reject "legal conclusions," "unsupported conclusions," "unwarranted inferences," "unwarranted deductions," "footless conclusions of law" and "sweeping legal conclusions in the form of factual allegations." *Morse*, 132 F.3d at 906. Moreover, courts should not assume that a plaintiff can prove facts it has not

alleged or that a defendant has violated laws in ways that have not been alleged. *See Associated Gen. Contractors of Calif., Inc. v. California State Council of Carpenters*, 459 U.S. 519, 526 (1983); *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 263 (3d Cir. 1998). After reviewing the *well-pled* allegations, if the complaint fails to state a claim upon which relief can be granted, it must be dismissed. Fed. R. Civ. P. 12(b)(6).

Colur World's Complaint fails to state a claim against SmartHealth for four main reasons.⁵ First, Colur World's Lanham Act, Section 43(a) claims (Counts I and II) fail because: (1) Colur World has not alleged that the color pink is not a functional feature of its nitrile gloves; and (2) Colur World has not factually pled how both the color pink and the word "pink" have acquired secondary meaning in the medical and dental glove market. Second, Colur World's statutory dilution claim (Count III) fails because Colur World has not pled any facts to show that its marks are famous or that they have been actually diluted. Third, Colur World's common law unfair competition claim (Count IV) fails for the same reasons as the Section 43(a) claims as described above. Lastly, Colur World's negligence per se claim (Count V) fails because: (1) the Federal Food Drug and Cosmetics Act (the "FDCA") does not provide a private right of action and cannot otherwise be the basis of a negligence per se claim in this case; and (2) Colur World has not alleged an actual injury as required to have standing to bring such a claim. For each of these reasons, Colur World's complaint should be dismissed.

⁵ Although Medisafe Technologies has not yet appeared in the case, each of these points would warrant dismissal of Color World's claims against Medisafe as well.

I. COLUR WORLD CANNOT STATE A SECTION 43(a) CLAIM (COUNTS I AND II).

Colur World alleges a violation of Section 43(a) of the Lanham Act in Counts I and II: Count I alleges false designation of origin or "passing off;" Count II alleges infringement of Colur World's common law trade dress (COLOR PINK mark) and common law PINK NITRILE mark. As a basis for both of its claims, Colur World alleges in essence that SmartHealth is using Colur World's marks by selling pink nitrile gloves for medical or dental use and by displaying the word pink on the packaging, and that this will, in turn, cause confusion. (Compl., Dkt #1, ¶¶ 27, 35-35, 38, 43-51.) As explained below, Colur World has failed to allege sufficient facts to support either claim, and is incapable of doing so.

A. Colur World Has Not Alleged and Cannot Allege the Color Pink Is Not a Functional Feature of Its Glove.

Section 43(a) proscribes the use of "any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which . . . is likely to cause confusion . . . as to the origin, sponsorship, or approval of his or her goods." 15 U.S.C. § 1125(a).

Under Section 43(a), trade dress can be protected only if it is not a functional feature. It must serve no purpose other than to identify the source of the product. *See TrafFix Devices, Inc. v. Marketing Displays, Inc.*, 532 U.S. 23, 29 (2001). Functionality has a broad definition – in fact, the U.S. Supreme Court and Third Circuit Courts have extended the scope of functionality to include aesthetically functional features. *See TrafFix Devices, Inc.*, 532 U.S. at 33; *Standard Terry Mills, Inc. v. Shen Mfg., Co.*, 803 F.2d 778, 781 (3d Cir. 1986) (window pane checkered design was aesthetically functional and therefore not protectable); *University of Pittsburgh v. Champion Prods., Inc.*, 566 F. Supp. 711, 720-21 (W.D. Pa. 1983) ("We do not believe,

however, that the use of Pitt's name on soft goods has acquired any special significance beyond allowing the garment's wearer to display his or her support for the school The insignia on these soft goods thus serve a real, albeit aesthetic, function for the wearer.").

In fact, a plaintiff must both plead and prove non-functionality to state a claim under Section 43(a). *Versa Products Co.*, 50 F.3d at 199. A court must dismiss any trade dress infringement claim that does not specifically and factually plead non-functionality. *Liko AB*, 2008 WL 2977869, at *5-7 (requiring party to re-plead non-functionality); *GNI Waterman, LLC v. A/M valve Co.*, No. CV F 07-0863, 2007 WL 2669503, at *6 (E.D. Cal. Sept. 7, 2007) (dismissing complaint for failure to allege non-functionality).

Colur World has not and cannot allege that its COLOR PINK trade dress is non-functional as Colur World or SmartHealth use the color pink on their nitrile gloves. The Complaint is devoid of any allegation limiting Colur World's use of the COLOR PINK *solely* as a source identifier, and not as a functional feature. (*See generally* Compl., Dkt #1.) The Complaint also does not allege that SmartHealth does not use the color pink on its nitrile gloves as an ornamental, aesthetic or otherwise functional feature. (*Id.*)

Colur World cannot plead these allegations because the color pink on nitrile gloves is, in fact, functional. As is evident from Exhibit B to the Complaint, SmartHealth markets the pink color as an integral and functional part of its PINK RIBBON, GLOVES OF HOPE campaign to promote breast cancer awareness and to raise money for breast cancer research. (Compl., Dkt #1, Exhibit B.) The color pink clearly has a functional role in this. *See Sabert Corp. v. Ullman Co.*, No. 99 Civ. 5030, 1999 WL 1115048, at *5 (S.D.N.Y. Dec. 7, 1999) (color of platter was "an attempt to mimic the "look" of real gold and silver and create a luxurious quality to the goods" and thus had functionality); *Publications Intern., Ltd., v. Landoll, Inc.*, 164 F.3d 337, 342 (7th

Cir. 1998) (gold color was visually appealing on the edge of a cook book, as it connotes opulence and makes the book more desirable); *Deere & Co. v. Farmhand, Inc.*, 560 F. Supp. 85, 98 (S.D. Iowa 1982) (because farmers prefer to match their green farm accessories to their green tractors, the color green on the farm accessories serve an aesthetic function). Colur World's Section 43(a) claim based on infringement of its alleged COLOR PINK mark therefore fails as a matter of law.

B. Colur World Has Not Adequately Pled, and Cannot Plead, Its Alleged Marks Have Achieved Secondary Meaning to Support a Violation of Section 43(a).

To state a false designation of origin claim⁶ or one for common law trademark infringement, a plaintiff must allege its mark has acquired a secondary meaning—its own distinctiveness⁷—such that the consuming public will likely be confused between the plaintiff's and defendant's products. *See* 15 U.S.C. § 1125(a); *AT&T Co.*, 42 F.3d at 1428; *A&H Sportswear, Inc. v. Victoria Secret Store, Inc.*, 237 F.3d 198, 210 (3d Cir. 2000).

⁶ A “false designation of origin” claim under Section 43(a) is essentially an allegation that a party engaged in the behavior of “passing off” or “palming off.” *See Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 778 (1992) (Stevens, J., concurring). This occurs when a party uses another's designation of origin to misrepresent its own goods or services. *AT&T Co.*, 42 F.3d at 1428.

⁷ Some marks are inherently distinctive and do not require a showing of secondary meaning. *See Qualitex Co. v. Jacobson Products Co.*, 514 U.S. 159, 162-63 (1995) (“[F]anciful,’ ‘arbitrary,’ or ‘suggestive’ words or designs, . . . almost automatically tell a customer that they refer to a brand.”). However, words describing the characteristics of goods with which they are associated (such as Colur World's descriptive PINK NITRILE mark), and colors associated with goods (such as Colur World's COLOR PINK trade dress) are not inherently distinctive. *See Wal-Mart Stores, Inc. v. Samara Bros., Inc.*, 529 U.S. 205, 211 (2000) (“[W]ith respect to at least one category of mark--colors--we have held that no mark can ever be inherently distinctive.” (*citing Qualitex Co.*, 514 U.S. 159 at 162-63)). *See also Swift Brothers v. Swift & Sons, Inc.*, 921 F. Supp. 267, 275 (E.D. Pa 1995) (“Descriptive marks are only protected from infringement if they have acquired ‘secondary meaning.’”).

Secondary meaning "is a new and additional meaning" that "customers associate . . . with a single, albeit anonymous, commercial source." 2 J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition § 15:1 (4th ed. 2009). When the alleged designation or mark is descriptive, as is "pink" when describing the color of nitrile gloves, a plaintiff bears a higher burden to establish secondary meaning. See *Commerce Nat'l Ins. Servs., Inc. v. Commerce Ins. Agency, Inc.*, 214 F.3d 432, 440-41 (3d Cir. 2000) ("CBI is also attempting to establish rights to a . . . descriptive term used by a variety of businesses in a variety of contexts. In these circumstances, the evidentiary bar must be placed somewhat higher."). In *Commerce Nat'l Ins. Servs., Inc.*, even though the plaintiff exclusively used the mark COMMERCE for 10 years in the relevant market and had acquired over \$100 million in assets during that time period, the Third Circuit found that this was insufficient to turn a descriptive mark into a source identifier. *Id.*

The burden is equally high when establishing that a color associated with a good has acquired secondary meaning. See *Erbe Electromedizin GMHB v. Canady Tech., LLC*, 529 F. Supp. 2d 577, 602-04 (W.D. Pa. 2007) (dismissing trade dress claim based on the color blue on surgical probe because plaintiff could not meet burden to establish secondary meaning).

1. Colur World Failed To Allege Its Marks Have Achieved Secondary Meaning.

Colur World claims that SmartHealth's use of the color pink on its nitrile gloves and the use of the word "pink" in describing the color of the gloves constitutes a false designation of origin, yet Colur World has not adequately pled that its own designations have acquired the necessary secondary meaning to establish likelihood of confusion.

A plaintiff is required to plead "[f]actual allegations [sufficient] to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555 (emphasis added). Colur World,

however, relies on conclusory labels, stating without factual support that it "use[s] the COLOR PINK Mark as a source of origin," that "the Colur World Marks have acquired trademark distinctiveness," and that as a result, SmartHealth's conduct will likely cause consumer confusion. (Compl., Dkt #1, ¶¶ 13, 20, 35, 43-45.) This is not sufficient, especially in light of the high burden to establishing secondary meaning for these types of designations. *See Douglas v. Osteen*, 560 F. Supp. 2d 362, 369-70 (E.D. Pa. 2008) (dismissing Section 43(a) claim because plaintiff did factually plead that its designation acquired secondary meaning); *Liko AB v. Rise Lifts, Inc.*, No. 07-5302, 2008 WL 2977869, at *5-7 (E.D. Pa. July 31, 2008) (requiring party to file amended complaint because it alleged a violation of Section 43(a) in conclusory fashion).⁸ By failing to factually plead secondary meaning, as the plaintiff in *Twombly*, Colur World has "not nudged [its] claims across the line from conceivable to plausible," and its false designation of origin and common law infringement claims in Counts I and II must therefore be dismissed. *See Twombly*, 550 U.S. at 555.

2. Colur World Is Incapable of Amending Its Complaint To Sufficiently Plead Secondary Meaning of Its Marks to Demonstrate Likelihood of Confusion.

Colur World's false designation of origin and common law infringement claims also must be dismissed because Colur World cannot allege that it has acquired secondary meaning in its COLOR PINK and PINK NITRILE marks and thus cannot allege likelihood of confusion. *See*

⁸ Courts throughout the federal circuits recognize the possible abuse of formulaic pleading in Section 43(a) claims, and, therefore, require plaintiffs to go beyond conclusory allegations. *See, e.g., Knights Armament Co. v. Optical Sys. Tech., Inc.*, 568 F. Supp. 2d 1369, 1376-77 (M.D. Fla. 2008) ("These sparse facts and conclusory allegations constitute a mere recitation of the elements of the cause of action for trade dress infringement, which is insufficient to survive a motions to dismiss."); *Jones Apparel Group, Inc. v. Piccone*, No. 94 CIV. 0754, 1994 WL 260767, at *3 (S.D.N.Y. June 8, 1994) (dismissing common law trademark infringement claim because plaintiff failed to plead facts to show secondary meaning).

Osteen, 560 F. Supp. 2d at 369 (dismissing claim, stating that a motion to dismiss a Section 43(a) claim must be granted if "no reasonable factfinder could find a likelihood of confusion on any set of facts"); *see also J.G. Wentworth, S.S.C. v. Settlement Funding, LLC*, No. 06-0597, 2007 WL 30115, at *8 (dismissing Section 43(a) claim "[b]ecause no reasonable factfinder could find likelihood of confusion").

Since May 2005, Colur World has sold pink, "subtle lavender," *and* blue nitrile gloves prominently bearing various different names – NITRASTRETCH, NITRAFLEX and 2ndSKIN. (Compl., Dkt #1, Exhibit A; June 5, 2006 Response to December 1, 2005 Office Action, Ex. 6, at Exhibit 3.) Colur World's trademark registration file and exhibits to its Complaint show an inconsistent color marketing scheme – with packaging of its PINK NITRILE gloves fluctuating between light pink, coral and most recently, white. (*Id.*) This inconsistent branding is wholly at odds with Colur World's conclusory allegation that "the Colur World Marks have acquired trademark distinctiveness." No reasonable factfinder could find that Colur World's marks have acquired the secondary meaning necessary to establish likelihood of confusion. *See The Antioch Co. v. Western Trimming Corp.*, No. 98- 3876, 1999 WL 777556, at *4 (6th Cir. Sept. 16, 1999) (holding that inconsistent branding is contrary to allegation of acquired secondary meaning); *R.M. Smit, Inc. v. Collins Ltd.*, No. 81-895, 1983 WL 51918, at *6 (W.D. Pa. May 5, 1983) (prominent private label marks precluded finding of secondary meaning).⁹

⁹ *See also Maharishi Hardy Blechman Ltd. v. Abercrombie & Fitch Co.*, 292 F. Supp. 2d 535, 541 (S.D.N.Y. 2003) ("A trade dress which is . . . inconsistent among its products cannot be distinctive."); *Walt Disney Co. v. Goodtimes Home Video Corp.*, 830 F. Supp. 762, 766 (S.D.N.Y. 1993) (denying trade dress protection to line of videocassettes because the overall look of the video packaging was inconsistent).

SmartHealth's extensive labeling of its own PINK RIBBON nitrile gloves also demonstrates that Colur World cannot plausibly allege likelihood of confusion. *See Versa Prod. Co. v. BiFold Company Ltd.*, 50 F.3d 189, 213 (3d Cir. 1995). Among other things, SmartHealth's prominent use of the marks PINK RIBBON and GLOVES OF HOPE and the personalized statement from its Vice President clearly notifies consumers that these gloves are sold by SmartHealth—not Colur World—and thus preclude any possibility of confusion as to the origin of the goods. (Compl., Dkt #1, Exhibit B.) This is especially true given the fact that the consumers of the gloves are sophisticated purchasers who select the gloves for use in medical and dental practices. They can competently determine the source of the gloves. *See Versa Prod. Co.*, 50 F.3d at 213. Colur World even admitted that its consumers are sophisticated in its June 8, 2006 Response to the USPTO Office Action, when it argued that its consumers would not confuse its PINK NITRILE mark a similar PURPLE NITRILE mark. (June 5, 2006 Response to Office Action December 1, 2005, Ex. 6, at p. 10.)

Because Colur World cannot allege that the COLOR PINK and PINK NITRILE marks have acquired a secondary meaning, it cannot plausibly claim that likelihood of confusion could arise between SmartHealth's and Colur World's gloves. As such, Colur World's Section 43(a) claims under Counts I and II fail as a matter of law.

II. COLUR WORLD CANNOT STATE A PENNSYLVANIA STATUTORY DILUTION CLAIM (COUNT III).

Colur World's Pennsylvania statutory dilution claim also fails as a matter of law. The Pennsylvania anti-dilution statute provides in part:

The owner of a mark which is famous in this Commonwealth shall be entitled, subject to the principles of equity . . . to an injunction against another person's commercial use of a mark or trade name if such use begins after the mark has become famous and causes

dilution of the distinctive quality of the mark and to obtain such other relief as is provided in this section

54 Pa. Cons. Stat. Ann. § 1124.

To prevail under this statute, a plaintiff must allege facts sufficient to show that the mark has inherent or acquired distinctiveness, that the mark is famous, and that as a result of the defendant's conduct, it suffered *actual dilution*. See *Pennzoil-Quaker State Co. v. Smith*, No. 2:05-cv-1505, 2008 WL 4107159 (W.D. Pa. Sept. 2, 2008) ("[A] plaintiff must plead . . . that . . . the plaintiff owns a famous mark that is distinctive, inherently or through acquired distinctiveness."); *McNeil Nutritionals, LLC v. Heartland Sweeteners, LLC*, 512 F. Supp. 2d 217, 238 (E.D. Pa. 2007), *aff'd in part, rev'd in part*, 511 F.3d 350 (3d Cir. 2007) ("[T]o succeed on a claim under the Pennsylvania anti-dilution statute, a plaintiff must still demonstrate actual dilution.").

As explained above, Colur World has not claimed that its alleged marks have acquired distinctiveness or secondary meaning to demonstrate a "famous" mark. See *supra* Section I.B. In addition, Colur World has not alleged any facts, nor can it, to show that its marks have been actually diluted or that SmartHealth's conduct caused this. Count III of Colur World's complaint must therefore be dismissed.

III. COLUR WORLD CANNOT STATE A COMMON LAW UNFAIR COMPETITION CLAIM (COUNT IV).

Colur World's common law unfair competition claims also fails as a matter of law. A claim of common law unfair competition in Pennsylvania is identical to a Section 43(a) claim. *Gideons Int'l, Inc. v. Gideon 300 Ministries, Inc.*, 94 F. Supp. 2d 566, 580-81 (E.D. Pa. 1999). Just as with a Section 43(a) claim, Colur World would need to plead and prove that the color pink is not functional and that Colur World's alleged marks have acquired secondary meaning.

Id. Because Colur World has not (and cannot) allege that its COLOR PINK mark is not functional or that its descriptive marks have acquired a secondary meaning, *see* Section I above, Colur World's common law unfair competition claim fails as a matter of law. As a result, this Court should similarly dismiss Count IV of Colur World's complaint.

IV. COLUR WORLD CANNOT STATE A NEGLIGENCE PER SE CLAIM (COUNT V)¹⁰

Colur World's negligence per se claim also fails. To serve as a basis for a negligence per se claim, a statute must: (1) protect a class of persons which includes the one whose interest is invaded; (2) protect the particular interest which is invaded; and (3) protect that interest against the kind of harm which has resulted. *Wagner v. Anzon, Inc.*, 453 Pa. Super. 619, 627, 684 A.2d 570 (Pa. Super. 1996). Colur World cannot establish these elements.

Colur World bases its negligence per se claim on an alleged violation of the FDCA, but there is no private right of action under the FDCA. *See In re Orthopedic Bone Screw Prod. Liab. Liti.*, 193 F.3d 781, 788 (3d Cir. 1999). Additionally, although some courts have found that the purpose of the FDCA is to protect injured *consumers* of drugs and medical devices, *see Cabiroy v. Scipione*, 2001 PA Super 29, ¶ 16, 767 A.2d 1078 (Pa. Super. 2001), no court has extended this protection to *competitors* attempting to privately police violations of the FDCA, as Colur World is attempting to do here. *See Eli Lilly & Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 477 (N.D.N.J. 1998) (dismissing competitor's claim attempting to privately enforce FDCA); *see also* 21 U.S.C. § 337 (enforcement actions may only be brought by the United States); *Valente v.*

¹⁰ Although Colur World's Count IV alleges acts by defendant Medisafe Technologies (Compl., Dkt #1, ¶¶ 65-67), it claims "Defendants'" acts have caused it injury. (Compl., Dkt #1, ¶ 68.) As a result, to the extent this Count is directed to SmartHealth, SmartHealth moves to dismiss this Count as well.

Safamor, S.N.C., 48 F. Supp. 2d 862, 876 (E.D. Wis. 1999) (recognizing narrow scope of negligence per se actions to protecting injured consumers of drugs and medical devices).

A competitor is not within the class of persons that the FDCA protects. *See Eli Lilly & Co.*, 23 F. Supp. 2d at 477. Because Colur World is a competitor of SmartHealth – not an injured consumer – it cannot privately enforce the FDCA through a negligence per se action.

Colur World's Count IV claim also fails because Colur World failed to allege an actual injury sufficient to give it standing to sue in this Court. *See Doe v. National Board of Medical Examiners*, 199 F.3d 146, 153 (3d Cir. 1999) (stating that plaintiff "incorrectly equate[d] a violation of a statute with an injury sufficient to confer standing. The proper analysis of standing focuses on *actual injury*, not on whether a statute was violated"). As a result, Colur World's claim in Count IV of its complaint also fails as a matter of law.

CONCLUSION

For each of the reasons set forth above, SmartHealth Inc. and SmartPractice respectfully request that the Court dismiss Colur World's complaint in its entirety.

Respectfully submitted,

POST & SCHELL, P.C.

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/s/ John W. Dornberger
JOHN W. DORNBERGER, ESQUIRE
Attorney I.D. No. 69293
17 North Second Street, 12th Floor
Harrisburg, Pennsylvania 17101
(717) 731-1970

Attorneys for Defendants,
SmartHealth, Inc. and SmartPractice